TABLE 5.—ESTIMATED ANNUAL REPORTING BURDEN FOR BIOLOGICS[1]—Continued

21 CFR Section	No. of Respondents	No. of Responses Per Response	Total Annual Responses	Hours per Response	Total Hours
312.110(b)	10	1.3	13	75	975
312.130(d)	1	1	1	0.5	0.5
Total Reporting Burden					5,009,597.5

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 6.—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR BIOLOGICS[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
312.52(a)	27	2.5	67	5	135
312.57(a) and (b)	1,253	2	2,506	100	125,300
312.62(a)	5,014	1	5,014	40	200,560
312.62(b)	8,200	12.2	100,000	40	328,000
312.160(a)	3,400	7.35	25,000	30 min	1,700
312.160(c)	320	1	320	0.5	160
Total Biologics Recordkeeping Hours					655,855
Total Biologics Burden Hours					5,665,452.5
Total Human Drugs Burden Hours					11,575,113
Total Combined Burdens					17,240,565.5

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: August 6, 1999

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 99–20846 Filed 8–11–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Criteria for Safety and Efficacy Evaluation of Oxygen Therapeutics as Red Cell Substitutes; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Criteria for Safety and Efficacy Evaluation of Oxygen Therapeutics as Red Cell Substitutes.'' This public workshop is intended to examine the current status of the safety of red cell substitutes at both the basic and preclinical science levels and review the clinical experiences gained by manufacturers in the course of the development of these products. The public workshop also is intended to address problems of efficacy evaluation and risk/benefit assessments in trauma and surgery.

Date and Time: The public workshop will be held on September 27, 1999, 8 a.m. to 5 p.m., and on September 28, 1999, 8 a.m. to 12:30 p.m.

Location: The public workshop will be held at the National Institutes of Health, Natcher Conference Center, Bldg. 45, Balconies A, B, and C, 45 Center Dr., Bethesda, MD.

Contact: Joseph Wilczek, Center for Biologics Evaluation and Research (HFM–350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6129, FAX 301–827–2843.

Registration and Requests for Oral Presentations: Early registration by Friday, September 10, 1999, is recommended. Mail or fax registration information (including name, title, firm name, address, telephone, and fax number) to Joseph Wilczek (address above). On-site registration, which will begin at 7 a.m., will be done on a space available basis on the day of the workshop. There is no registration fee for the workshop. Space is limited, therefore, interested parties are encouraged to register early. If you need special accommodations due to disability, please contact Joseph Wilczek at least 7 days in advance. Requests for oral presentations should be sent by September 13, 1999, to Abdulilah Alayash, Center for Biologics Evaluation and Research, Division of Hematology, Bldg. 29, rm. 112, 8800 Rockville Pike, Bethesda, MD 20892, 301–827–3813, FAX 301–435–4034, or e-mail ''Alayash@cber.fda.gov''.

Agenda: The public workshop is intended to discuss a variety of issues concerning the safety and efficacy of red blood cell substitutes. The goals of the public workshop are to: (1) Review current understanding of toxicity issues, (2) define clinical endpoints for clinical trials in hemorrhagic shock and elective surgery, (3) consider whether physiological endpoint(s) could be used as surrogates in lieu of mortality and/or morbidity, and (4) discuss the therapeutic ''risk vs. benefit'' in using hemoglobin and fluorochemical-based products in trauma and surgery.

Transcripts: Transcripts of the public workshop may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A– , Rockville, MD 20857, approximately 15 working days after the public workshop at cost of 10 cents per page. The public workshop transcript will also be available on the Center for Biologics Evaluation and Research website at ''http://www.fda.gov/cber/minutes/workshop-min.htm''.

Dated: August 6, 1999

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

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